Journal of Psychosomatic Research 76 (2014) 341–351

Contents lists available at ScienceDirect

Journal of Psychosomatic Research

Review

Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials

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ARTICLE INFO

Article history:
Received 29 November 2013
Received in revised form 25 February 2014
Accepted 26 February 2014

Keywords:
Mindfulness
MBSR
MBCT
Vascular disease
Systematic review
Meta-analysis

ABSTRACT

Objective: To determine the effectiveness of mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT) on psychological and physical outcomes for people with vascular disease.
Design: Systematic review and meta-analysis of randomised controlled trials.
Data sources: AMED, CINAHL, EMBASE, British Nursing Index, Medline, Web of Science, PsycINFO, Cochrane Database of Systematic Reviews, Central, Social Sciences Citation Index, Social Policy and Practice, and HMIC from inception to January 2013.
Review methods: Articles were screened for inclusion independently by two reviewers. Data extraction and quality appraisal were performed by one reviewer and checked by a second with discrepancies resolved by discussion with a third if necessary. Random-effects meta-analyses were performed.
Results: Nine articles (from eight original randomised controlled trials) met eligibility criteria and were included in the final review. In total, 578 participants were enrolled across the trials, with participants presenting with prehypertension/hypertension (n = 3 trials), type 1 or 2 diabetes (n = 2), heart disease (n = 2) and stroke (n = 1). Meta-analyses, using standardised mean differences, showed evidence of reductions in stress (−0.36; 95% CI −0.67 to −0.09; p = 0.01), depression (−0.35; 95% CI −0.53 to −0.16; p = 0.003) and anxiety (−0.50; 95% CI −0.70 to −0.29; p < 0.001). Effects on physical outcomes (blood pressure, albuminuria, stress hormones) were mixed.
Conclusion: Whilst populations with vascular disease appear to derive a range of psychological benefits from MBSR/MBCT intervention, the effects on physical parameters of disease are not yet established. More robust studies, with longer term follow-up, are required to ascertain full effectiveness of such intervention.

Contents

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http://dx.doi.org/10.1016/j.jpsychores.2014.02.012
0022-3999/

Introduction

Vascular disease accounts for over a quarter of all deaths in westernised countries [1,2]. Moreover, both the disease itself and its associated clinical events, such as myocardial and cerebral infarction, are significant and distressing life events. Depression, anxiety, and psychological distress, in turn, are independent risk factors for vascular disease morbidity and mortality [3,4]. In recognition of this, many guidelines for conditions such as cardiac rehabilitation and hypertension include stress management as a part of recommended therapy [5,6]. Equipping patients with skills and coping strategies to help reduce or manage perceived psychological stress may represent an important secondary prevention intervention. Although the most effective mode of stress reduction therapy is yet to be established, increasing recognition is being given to mindfulness therapy [7].

Mindfulness is defined as the capacity to intentionally be in the present moment without judgement [8]. Two of the main mindfulness-based approaches, which aim to cultivate mindfulness therapeutically, include Mindfulness-Based Stress Reduction (MBSR), and Mindfulness-Based Cognitive Therapy (MBCT). MBSR is a structured, manualised treatment programme originally developed for the management of chronic pain and now used widely to reduce psychological morbidity associated with chronic illnesses and to treat emotional and behavioural disorders [9]. MBCT, derived from MBSR, was designed for people with a history of recurrent depression to help prevent future recurrences [10]. The standard practice for both therapies is a group-based programme held over 8–10 weeks, with a weekly two hour session, inclusion of daily homework in the practice of mindfulness and a one day retreat [7]. MBSR and MBCT have been demonstrated to be effective therapies to treat anxiety and depression, in both clinical and non-clinical populations [11–13]. A meta-analysis on the effects of MBSR on mental health of adults with chronic disease showed small but positive effects on depression anxiety and psychological distress [14]. In addition, MBSR may also improve physiological aspects of vascular disease [15]. Indeed, randomised controlled studies of MBSR intervention have been shown to reduce blood pressure in low-income African-American older adults [16], and in community dwelling participants with stress related complaints [17].

In vascular disease, pilot and observational studies of MBSR and MBCT intervention have been associated with improvements in perceived health, quality of life and physiological responses in stroke survivors [18,19], and in reductions of patient reported diabetes-related distress [20]. MBSR has also been associated with lowered blood pressure and better glycaemic control in patients with diabetes [21]. However, with a predominance in the evidence base of small non-randomised studies, the efficacy and treatment effects are as yet to be fully understood. The purpose of this systematic review was to establish whether MBSR and MBCT are effective in the management of both depressive and physical symptoms in individuals with vascular disease and those at high risk of vascular disease.

Methods

The systematic review was conducted following the general principles published by the NHS Centre for Reviews and Dissemination [22]. The protocol for this review was developed in consultation with two experts in MBCT and MBSR (see http://clahrc-peninsula.nihr.ac.uk/effectiveness-of-mindfulness-based-stress-reduction-and-mindfulness-based-cognitive-therapy-in-vascu.php). The protocol is registered with Prospero (registration no. CRD4201300385).

Types of studies

Only randomised controlled trials (RCTs) were included.

Types of participants

For inclusion, participants had to have vascular disease, which for the purposes of this review included coronary heart disease, angina, myocardial infarction, stroke and peripheral vascular disease. People at a high risk of developing vascular disease including those with diabetes, hypertension and hypercholesterolaemia were also included.

Types of interventions

Interventions that were described as either MBSR or MBCT were included for review. Shortened versions or amended versions of MBSR/MBCT interventions were also included, but interventions that were based on mindfulness but were not specific programmes of MBSR/MBCT were excluded.

Outcome measures

Both quantitative and qualitative outcomes from RCTs were considered. Quantitative outcomes of interest were: psychological outcomes (e.g. anxiety, depression), physical outcomes (e.g. blood pressure, markers of disease status), measures of health service utilisation and quality of life. To be eligible for inclusion, studies had to report on either psychological or physical outcomes (or both). Qualitative outcomes of interest were views on, and experience of, individuals with vascular disease receiving MBCT/MBSR.

Table 1
Summary of basic study characteristics

Source, country	Study design & comparator	Participants	Vascular condition	Intervention	Length of Intervention	Outcomes
Blom (2012) Canada	RCT with waitlist control	101 adults (38 males, 63 females), mean age of 55 (11) yrs	Stage 1 unmedicated hypertension	MBSR [The HARMONY Study]: 2.5 h/week with homework of 45 min/day. Included a 1 day retreat	8 weeks	Primary: mean awake and 24 h ambulatory SBP and DBP
de la Fuente (2010) Spain	RCT with waitlist control	19 adults (8 males, 11 females), with mean age of 44 (11) yrs	Stage I or II essential unmedicated hypertension	MBSR: 90 min/week plus 30 min/day homework	10 weeks	Primary: resting SBP and DBP
Hartmann (2012) Germany	RCT with TAU control	110 adults (86 males, 24 females), with age range of 30–70 yrs	Type 2 diabetes (>3 years) with albuminuria	MBSR [The HEIDIS-Study]: 1/week , and a booster session after 6 months	8 weeks (*plus follow-up at 1 year)	Primary: albuminuria Secondary: SBP and DBP, depression, stress, health status
Hughes (2010) USA	Pilot RCT with progressive muscle relaxation control	56 adults (24 males, 32 females) with mean age of 50 (6) yrs	Unmedicated pre-hypertension	MBSR: 2.5 h/week with homework of 45 min/day	8 weeks	Primary: clinic SBP and DBP Secondary: ambulatory SBP, DBP
Johansson (2012) Sweden	RCT with waitlist control	21 adults (9 males, 12 females) with age range of 30–65 yrs	Stroke >1 year ago *with* mental fatigue	MBSR: 2.5 h/week, and home practice of 45 min/day. Included a 1 day retreat	8 weeks	Primary: mental fatigue, anxiety & depression Secondary: information processing and attention
Nyklíček (2012) The Netherlands	RCT with self-help booklet control	114 adults (88 males, 26 females) with a mean age of 55 (7) yrs	Heart disease: percutaneous coronary intervention	MBSR [The MindfulHeart trial]: 2 h/week plus an additional evaluation session plus homework of 30 min/day	3 weeks	Primary: anxiety, depression, stress, vitality, QOL Secondary: mindfulness
Robert McComb (2004) USA[a]	RCT with waitlist control	18 women with a mean age of 60 (6) yrs	Heart disease: angina/CHF, hypertension, valve disorders	MBSR: 2 h/week plus additional daily homework practice	8 weeks	Primary: stress hormones, sub-maximal exercise response and physical functioning
Tacon (2004) USA[a]	RCT with waitlist control	18 women with a mean age of 60 (6) yrs	Heart disease: angina/CHF, hypertension, valve disorders	MBSR: 2 h/week plus additional daily homework practice	8 weeks	Primary: anxiety Secondary: emotional control, coping, health locus of control
Van Son (2013) The Netherlands	RCT with waitlist control	139 adults (70 males, 69 females) with a mean age 56/57 (13) yrs,	Types 1 & 2 diabetes *with* low emotional well-being	MBCT & MBSR fusion [The DiaMind study]: 2 h/week and homework practice for 30 min/day	8 weeks	Primary: stress, anxiety & depression, mood, diabetes distress Secondary: QoL, HbA1c

MBSR: Mindfulness-based stress reduction.
MBCT: Mindfulness-based cognitive therapy.
[a] Same study.

Table 2
Summary of author reported outcomes of MBCT/MBSR interventions

Study	Intervention	Vascular condition	Outcome measures & assessment tools	Effect on outcomes (data presented for baseline and post intervention only)
Blom (2012)	MBSR	HT	24 h SBP and DBP[a]	No effect on BP at 8/52 Δ SBP mm Hg (mean, SD) between intervention (INT) and control (C) was 0.0 (±7.2) for SBP, p = 0.96 Δ DBP mm Hg (mean, SD) between INT and CON was 0.4 (±4.7) for DBP, p = 0.60
de la Fuente (2010)	MBSR	HT	Resting SBP and DBP[a]	Significant reduction in BP post intervention at 10/52 [and remaining at 4/12]. Δ SBP mm Hg: CON 157.8 (6.8) to 158.5 (6.7), INT 156.4 (7.5) to 129.1 (5.2), p < 0.001 Δ DBP mm Hg: CON 97.4 (3.8) to 98.5 (4.3), INT 97.1 (4.9) to 82.6 (6.3), p < 0.001
Hughes (2010)	MBSR	HT	Resting SBP and DBP[a]	Significant reduction in clinic SBP and DBP with intervention compared to PMR at 8/52 Δ SBP mm Hg: PMR 128.8 (6.4) to 128.1 (9.1), INT 130.2 (6.3) to 125.3 (7.4), p = 0.02 Δ DBP mm Hg: PMR 78.5 (6.1) to 79.5 (7.9), INT 77.3 (4.8) to 75.4 (5.1), p < 0.01
Hartmann (2012)	MBSR	DM	Albuminuria, HbA1c & 24 h SBP and DBP[a] Stress and depression (Patient Health Questionnaire) Subjective health (SF-12)	No effect on any outcome at 8/52. (At 1 yr, significant reduction in DBP, depression & perceived mental health status) Δ albuminuria (median mg/24 h): CON 45.0 to 66.5, INT 59.6 to 42.8, p = 0.42 Δ HbA1c % (mean, SE):CON 7.3 (0.1) to 7.1 (0.1), INT 7.3 (0.1) to 7.2 (0.1), p = 0.70 Δ SBP mm Hg (mean, SD):CON 139.1 (14.3) to 140.8 (15.0), INT 142.3 (18.2) to137.6 (14.4) p = 0.27 Δ DBP mm Hg (mean, SD):CON 80.0 (7.5) to 80.7 (8.6), INT 80.5 (8.0) to 77.7 (7.9), p = 0.06
Johansson (2012)	MBSR	S	Mental fatigue (MFS)[a] Anxiety and depression (CPRS)[a] Information processing and attention	No significant effects of intervention at 8/52. Significant improvements in cognitive tests for intervention but not controls. Δ mental fatigue: CON no change, INT reduction p = 0.06 Δ anxiety and depression: NS Δ trail making test: INT faster than CON, p = 0.01
Nyklíček (2012)	MBSR	HD	Anxiety & depression (SAD-4)[a] Stress (Perceived Stress Scale)[a] Vitality (GMS), QOL (WHO)	No significant effects (author adjusted for age, education and comorbidity) on stress and anxiety & depression at 4/52. No effects on vitality. Significant effects of psychological QOL, but not physical QOL. Mindfulness increased in intervention only Δ stress: CON 20.4 (0.9) to 18.4 (1.1), INT 22.9 (0.9) to 18.4 (1.1) p >0.10 Δ anxiety & depression: CON 3.01 (0.49) to 2.80 (0.42), INT 4.03 (0.49) to 2.42 (0.41) p = 0.072
Robert McComb (2004)[b]	MBSR	HD	Resting stress hormones (cortisol and catecholamines — standardised methods), physical functioning (SF-36)	No significant main effects or interaction for resting stress hormones or physical function. Δ catecholamines: CON 598 (434) to 576 (329), INT 523 (164) to 484 (204), NS Δ cortisol: CON 21.0 (5.6) to 21.2 (6.4), INT 19.7 (7.9) to 15.8 (7.3), NS Δ physical functioning: CON 38.3 (11.6) to 35.3 (9.8), INT 40.6 (13.7) to 42.1 (14.1), NS
Tacon (2004)[b]	MBSR	HD	Anxiety (STAI), emotional control (CECS), coping (PRSOC),	Significant effects observed for anxiety, emotional control and coping. Δ anxiety: CON 43.2 (12.3) to 43.5 (13.3), INT 37.9 (10.9) to 29.1 (7.4), p < 0.01 Δ suppress emotion: CON 53.7 (4.5) to 55.5 (6.0), INT 62.1 (4.9) to 57.4 (5.0), p < 0.02 Δ coping: CON 14.1 (5.3) to 16.2 (3.9), INT 15.3 (2.3) to 13.8 (1.8), p < 0.03
Van Son (2013)	MBCT & MBSR	DM	Stress (Perceived Stress Scale)[a] Anxiety (HADS)[a] Depression (HADS)[a]	Intervention resulted in sig reduction in stress, depressive symptoms and anxiety at 8/52 Δ stress: CON 20.5 (5.59) to 19.6 (6.7), INT 19.5 (6.0) to 14.2 (6.9), p < 0.001 Δ anxiety: CON 9.2 (3.6) to 8.7 (4.1), INT 8.4 (3.3) to 6.3 (3.5), p = 0.02 Δ depression: CON 8.9 (3.9) to 8.5 (4.7), INT 7.9 (3.8) to 5.4 (4.1), p < 0.01

NS: not significant (no data presented).
DM: diabetes.
HT: hypertension.
HD: heart disease.
S: stroke.
[a] Primary outcome measure.
[b] Same study.

1 Aneurysm.tw. (58873)
2 Angi*.tw. (382370)
3 Aort*.tw. (199604)
4 Apoplectic.tw. (325)
5 Arteri*.tw. (447334)
6 Blood vessel*.tw. (51806)
7 Brain injur*.tw. (31869)
8 Brain attack*.tw. (198)
9 Capillary Leak Syndrome*.tw. (442)
10 Cardiac*.tw. (397253)
11 Cardio*.tw. (453612)
12 Cerebr*.tw. (342061)
13 (Chronic adj2 disease*).tw. (93390)
14 (Chronic adj2 illness*).tw. (11202)
15 Compartment Syndrome*.tw. (4241)
16 Coronary.tw. (276449)
17 Cva.tw. (1677)
18 Diabet*.tw. (364592)
19 Embolism.tw. (37807)
20 Endoleak.tw. (1792)
21 Endothelial dysfunction.tw. (13821)
22 extravasation.tw. (10848)
23 Graft occlusion.tw. (1170)
24 Hand-Arm Vibration Syndrome*.tw. (266)
25 heart*.tw. (577691)
26 Hemorrhoid*.tw. (3197)
27 Hemostatic Disorder*.tw. (453)
28 Hepatic Veno-Occlusive Disease*.tw. (481)
29 hypercholesterolaemia.tw. (3873)
30 Hyperemia.tw. (7275)
31 Hypertension.tw. (252482)
32 Hypotension.tw. (39000)
33 Isch?emic.tw. (157198)
34 Macroangiopathy.tw. (857)
35 myocardial.tw. (239289)
36 Peripheral arterial disease*.tw. (5041)
37 Prehypertension.tw. (694)
38 Pulmonary Veno-Occlusive Disease*.tw. (234)
39 Reperfusion Injury.tw. (17748)
40 Retinal Vein Occlusion.tw. (2502)
41 Scimitar Syndrome*.tw. (444)
42 Splenic Infarction.tw. (547)
43 Spontaneous portosystemic shunt.tw. (8)
44 Stroke*.tw. (125634)
45 Superior Vena Cava Syndrome*.tw. (1258)
46 Telangiectasis.tw. (568)
47 Thoracic Outlet Syndrome*.tw. (1251)
48 Thromboembolism.tw. (20765)
49 Thrombosis.tw. (87918)
50 Varicocele.tw. (3269)
51 Varicose Vein*.tw. (5256)
52 Vascul*.tw. (450768)
53 Vaso*.tw. (162129)
54 Vein graft disease*.tw. (246)
55 Venous Insufficiency.tw. (3427)
56 exp Diabetes Mellitus/ (286976)
57 exp Vascular Diseases/ (1242741)
58 exp Stroke/ (73488)
59 exp Cardiovascular Diseases/ (1746906)
60 exp Chronic Disease/ (208938)
61 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 (3643098)
62 mbsr*.tw. (180)
63 mbct*.tw. (105)
64 mindfulness*.tw. (1227)
65 exp Meditation/ (1242)
66 62 or 63 or 64 or 65 (2071)
67 61 and 66 (343)

Fig. 1. Search strategy (example shown for Medline).

Search strategy

The search strategy was developed by an information specialist in consultation with topic and method experts. The strategy used a combination of MeSH terms and free text terms. An illustration of the search strategy used on MEDLINE can be seen in Fig. 1. Eleven databases were searched from inception to January 2013: AMED, CINAHL, Embase, British Nursing Index, MEDLINE, Web of Science, PsycINFO, Cochrane Database of Systematic Reviews, Central, Social Policy and Practice, and HMIC. No date or language restrictions were used. No date or language restrictions were used. Hand searching of key journals (Journal of Psychosomatic Research, and Psychosomatic Medicine), identified as prominent in the search and the bibliographies of included studies, was also done for relevant articles. Searching of grey literature was also undertaken on the websites http://mindfulnessteachersuk.org.uk and http://www.mindfulexperience.org/. Forward and backward citation chasing of each included article was conducted. Two reviewers (RA, RW or AB) independently screened titles, abstracts and full texts using the eligibility criteria. Discrepancies were discussed and resolved by a third reviewer (RW or AB) where necessary.

Risk of bias and study quality

The methodological quality of each paper was assessed using the Cochrane 'risk of bias' tool [23]. The tool includes six key criteria against which potential risk of bias is judged: adequacy of allocation sequence

generation; adequacy of allocation concealment; blinding of participants, personnel or outcome assessors; completeness of outcome data; selectivity of outcome reporting, and other biases. In addition to the Cochrane risk of bias tool, four additional aspects of quality relating to reporting of eligibility criteria, similarity of baseline characteristics, compliance with intervention and data collection tool validity were assessed. Quality was assessed by one reviewer (RA, AB, or RW), with judgements checked by a second (RW, RA, or AB). Any discrepancies were discussed and resolved.

Data collection

Data on the study design, the setting, the population, the intervention, the outcomes and results, and risk of bias were collected using a standardised, piloted data extraction form. Data were extracted by one of two reviewers (RA, AB) and fully checked by another (RA or RW). As we were interested in any modifications made to the standard MBSR or MBCT intervention, to assess whether modifications impacted on effects, authors of included studies were also contacted for information with a request for the manuals supporting their intervention.

Data analysis and synthesis

Random effect meta-analyses were performed where we had sufficient data from RCTs assessing the same clinical outcome. Authors of included studies were contacted to provide additional data where required, this included group mean and standard deviations, correlations and, in one case, raw data. Follow-up time was consistent across almost all studies, eight weeks for all except one (ten weeks). Pooling was performed on the outcomes measured immediately following the intervention (only two studies had additional longer term assessment). As we used a random-effects model for the meta-analyses, the weightings for each study were determined not only by the size of each study included, but also by between-study heterogeneity. All studies analysed change in outcome between baseline and follow-up. Unadjusted summary data were used to calculate standardised mean differences (SMDs). We calculated the mean change in each group based on mean differences between baseline and follow-up and the standard deviation was pooled across the treatment and control groups, taking correlation between baseline and follow-up into account. As all the outcomes were continuous, pooled effects are reported as standardised mean differences with 95% confidence intervals. Where there were differences in the number of individuals contributing to baseline and follow-up summary statistics we used the average sample size. Where the mean change from baseline, standard deviation (SD) and sample size for each trial arm were reported in the papers we used the *t*-test to calculate the mean difference between arms and standard error. In the meta-analysis for blood pressure, in which the mean and SD at baseline and follow-up were reported for each group and raw data were not available, correlations between baseline and follow-up from a comparable study [24] (SBP measurement correlations 0.73 and 0.75, DBP correlations 0.77 and 0.77, for treatment and control groups respectively) were used to help calculate the standard error. For another study [25] in the meta-analysis for anxiety, post intervention values only were used, as within study or comparable study correlation data for the State-Trait Anxiety Inventory (STAI) outcome measure were not available. Another study [26] reported assessing anxiety and depression using two complementary instruments: the Hospital Anxiety and Depression Scale (HADS) and the Profile of Mood States (POMS). We did not combine the HADS and POMS effect sizes as the correlation between the two measures was not known [27] (requested from author but not provided). HADS was therefore used for the meta-analyses (the authors citing this as the more widely used and well known instrument), and sensitivity analyses were performed to assess the effect on the pooled effect with inclusion of POMS instead of HADS.

Heterogeneity across estimates was quantified using the I-squared statistic and the p-value for the Q-test was used to test for evidence of heterogeneity [28]. Data analysis was carried out using Stata [Stata Corporation. Stata Statistical Software. Release 12.1. College Station,TX, 2011] and Review Manager (RevMan) Version 5.2 software (http://ims.cochrane.org/revman). Synthesised results are presented by outcome type. Effect sizes are expressed as small (0.2–0.5), moderate (0.5–0.8) and large (>0.8) [29]. Where pooling was not appropriate or possible, the findings have been summarised in narrative form.

Results

The electronic searches found a total of 1280 results, and after title and abstract screening, 55 full texts were retrieved for closer examination. A total of nine articles (from eight original randomised controlled trials) were included in the final review, with two identified from forward and backward citation chasing (none were identified from hand searching of key journals). Reasons for exclusion at the full text stage can be seen in Fig. 2.

Study characteristics

The nine articles (from eight trials) that met inclusion criteria were published from 2004 onwards, with five published in the past year alone (2012/2013) (see Table 1). The eight trials were conducted in Canada, Germany, Spain, Sweden, The Netherlands (n = 2) and the United States of America (n = 2). Trial size ranged from 18 to 139 participants, with four of the eight trials having >100 participants [26,30–32]. In total, 578 participants were enrolled across the eight trials. Participants were those presenting with prehypertension or hypertension (n = 3 trails), type 1 or 2 diabetes (n = 2), heart disease (n = 2) and stroke (n = 1). Five trials employed a wait-list control design, two an active control design with either provision of a self-help booklet or attendance at progressive muscle relaxation classes, and one a standard control arm offering treatment as usual. The mean age of participants recruited ranged from 44 to 60 years, and all bar one trial [25,23] (100% female) was mixed sex, with the percentage of females ranging from 22 to 62%. In six out of the eight trials, there was no prerequisite for participants to present with any psychopathology prior to randomisation; eligibility was based on physical condition alone [24,25,30–34]. In one trial [26], participants were eligible for recruitment only from outpatient diabetes clinics if they had a low level of emotional well-being (scored <13 on the WHO-5 well being index), and in another [35], participants had a co-morbidity of mental fatigue.

Intervention characteristics

The frequency and dose of intervention time for the participants was clearly reported for seven of the eight trials. There was little variation amongst the interventions: all were group based, and groups met once a week for a range of 1.5–2.5 h/week, with the addition of daily homework for 30-45 min for six days per week (reported for seven out of the eight trials). Most trials involved eight weeks of intervention (n = 6), with one trial reporting ten weeks [34], and one trial evaluating a shortened version of three weeks [32]. Three trials reported making adaptations to the standard programme: two involving outpatients with diabetes [26,31] that included education and practices for difficult thoughts and feelings related specifically to diabetes, and one for stroke patients [35] that allowed extra time to pause and reflect. Only two manuals were received from initial requests, with two other authors reporting no change to standard intervention, other than that already reported in the manuscript. Only two [30,35] of the eight trials included the provision of a one day retreat (typically considered to be part of the standard MBSR programme) in addition to the weekly classes. Seven trials [24,25,30–35] were MBSR interventions, and one, the DiaMind study [26], was a fusion of MBCT and MBSR therapy.

Outcomes

Five of the studies reported physical primary outcomes: blood pressure [24,30,35], albuminuria [31] and stress hormone levels [33] - see Table 2 The remaining four studies reported psychological primary outcomes: anxiety and depression and/or stress [25,26,31] and mental fatigue [35]. Only two studies reported on both psychological and physical outcomes [26,31]. Secondary outcomes varied according to clinical population and trial objective, comprising predominantly a variety of disease status markers (diastolic blood pressure (DBP), systolic blood pressure (SBP), glycosylated haemoglobin (HbA1c)) and psychological and physical health outcomes (anxiety and depression, perceived stress, emotional well-being, coping, and health-related quality of life). No trials reported qualitative outcomes.

Study quality (risk of bias)

A summary of the risk of bias is presented in Fig. 3. Despite all being described as randomised controlled trials, for the majority of the studies, the methods of randomisation, particularly how the random sequence was generated, were unclear. Furthermore, whilst eligibility criteria were described well, only one study reported participation rates of those who were deemed eligible, raising the possibility of selection bias across

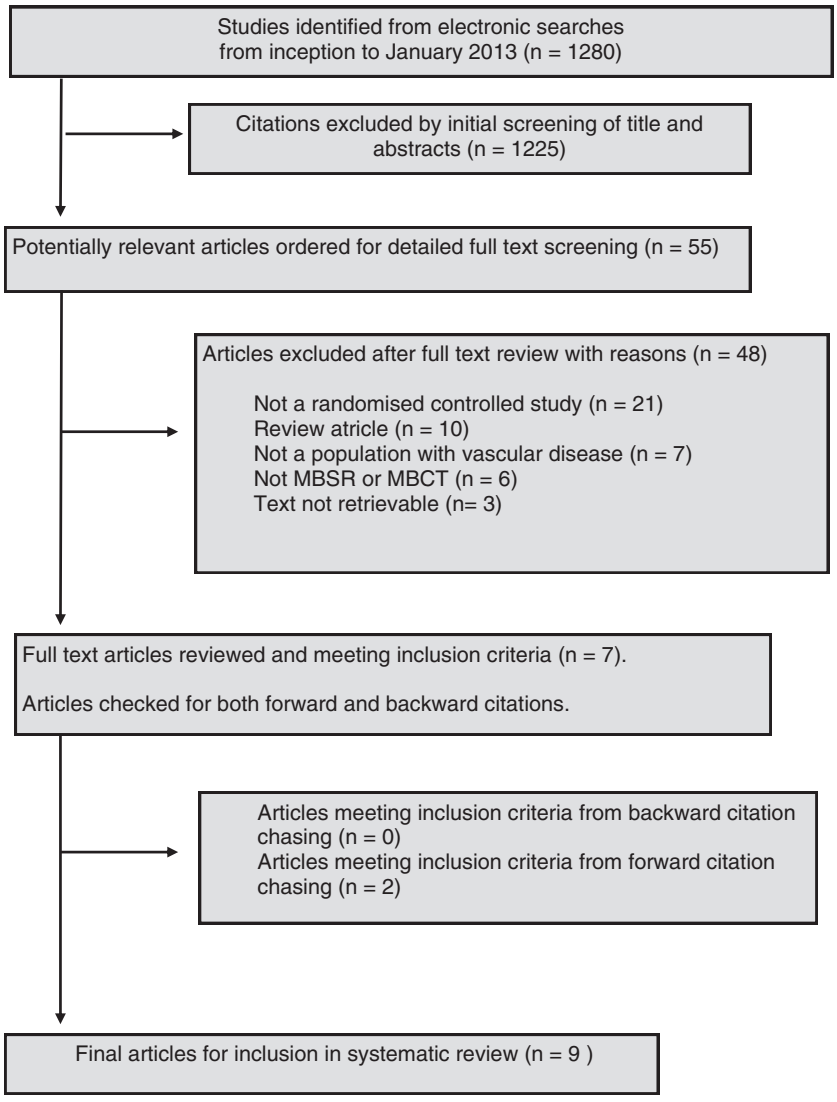

Fig. 2. Flow chart of search results and article retrieval.

the studies. Due to the nature of this type of intervention, all of the studies were also at risk of bias with participants clearly aware of their group allocation.

For most of the studies, outcome data were complete or missing data were accounted for adequately, and data collection tools were deemed valid and reliable. However, compliance with the intervention was reported in only two of the eight trials, with drop-out rates ranging from 5% to 26% across the studies. For the majority of the studies insufficient information was provided to evaluate the blinding of assessors; only one study explicitly reported that assessors were blinded to group assignment.

Synthesis by outcome

Psychological

Overall, MBSR/MBCT participation resulted in significant favourable small to moderate effects for psychological outcomes across a variety of clinical populations. Using unadjusted data, small but significant, beneficial effects on stress (SMD −0.38, 95% CI −0.67 to −0.09, p = 0.01) and depression (SMD −0.35, 95% CI −0.53 to −0.16, p < 0.001) were observed across three (n = 363) and four trials (n = 384) respectively (see forest plots in Figs. 4 and 5). These effects were observed in people with diabetes (the DiaMIND study and the HEIDIS study) [26,31], with heart disease who had undergone coronary perfusion (the MindfulHEART study) [32] and people who had been suffering from pathological mental fatigue for one year post stroke (included in the depression analysis only) [35]. Assessment of stress was derived from the Perceived Stress Scale [26,32] and the Patient Health Questionnaire (PHQ) [31]. Assessment of depression was derived from the PHQ [31], the HADS [26], the Symptoms of Anxiety and Depression index (SAD-4) [32] and the Comprehensive Psychopathological Rating Scale (CPRS) [35]. Sensitivity analyses using the 'depression-dejection' outcome from POMS instead of the HADS depression scores for the DiaMIND study showed no difference in the overall effect in the meta-analysis reported above; SMD −0.36, 95% CI −0.56 to −0.16, p < 0.001.

Using the unadjusted data for our meta-analysis, the effects on both stress and depression appear evident even in the brief version of the MBSR MindfulHEART intervention. However, when the authors of this shortened intervention fully adjusted their data for baseline values, age, education and comorbidity, the effects were only significant for those <60 yrs of age [32].

A significant moderate effect was also observed for anxiety (SMD −0.50, 95 %CI −0.70 to −0.29, p < 0.001), as shown in Fig. 6. This effect was observed across four studies (n = 269) in people with heart disease [25,33], diabetes [26] and those recovering from a stroke [35]. Anxiety was assessed with a different tool in each study; HADS, SAD-4, CPRS, and the State-Trait Anxiety Inventory (STAI). Again, sensitivity analyses using the 'anxiety-tension' outcome from POMS instead of the HADS anxiety scores for the DiaMIND study showed little difference in the overall effect in the meta-analysis reported above; SMD −0.55, 95% CI −0.75 to −0.36, p < 0.001.

All five studies included in the analyses on the primary psychological outcomes also reported significant improvements in a variety of measures of well-being and quality of life. In the DIAMIND study [26], significant beneficial effects were observed immediately after intervention for both self-reported mental and physical quality of life (SF12), but not for disease-specific distress (measured with the Problem Areas in Diabetes Survey),

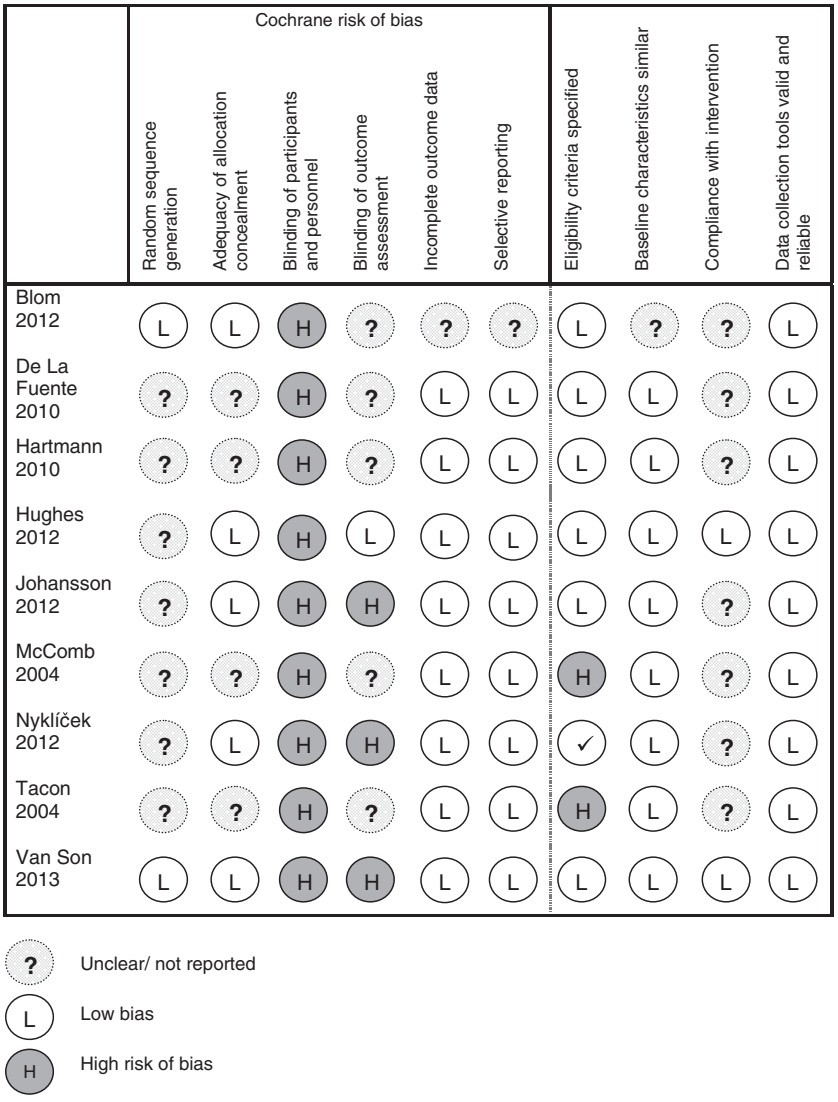

Fig. 3. Risk of bias for included studies.

which was attributed to low levels at the start of the trial. The MindfulHEART study [32] observed improvements in self-reported psychological and social quality of life (Seattle Angina Questionnaire) respectively, but no effect on physical quality of life. Whilst the HEIDIS study [31] found no change in self-reported mental or physical quality of life (using the SF-12) post intervention, at one year post intervention, significant effects were observed for perceived mental quality of life. Tacon et al. [25] also reported significant improvements in emotional control and coping in females with heart disease, though in the same group there was no effect on the participants' perception of their health locus of control.

Physical

Four RCTs assessed the effects of MBSR intervention on systolic blood pressure (SBP) and diastolic blood pressure (DBP) in participants with unmedicated prehypertension (SBP 120–139 mm Hg or DBP 80–89 mm HG) [24], unmedicated grade 1 hypertension (24 h SBP >130 mm Hg or 24 h DBP > 80 mm HG) [30], a mixture of unmedicated grade 1 (140–159 mm Hg SBP, 90–99 mm Hg DBP) and 2 (160–179 mm Hg SBP, 100–109 mm Hg DBP) hypertension [34] and a group at high risk of diabetes complications [31]. Two of the trials employed a waiting list control [30,34], one used an active control programme of progressive muscle relaxation (PMR) [24] and one treatment as usual

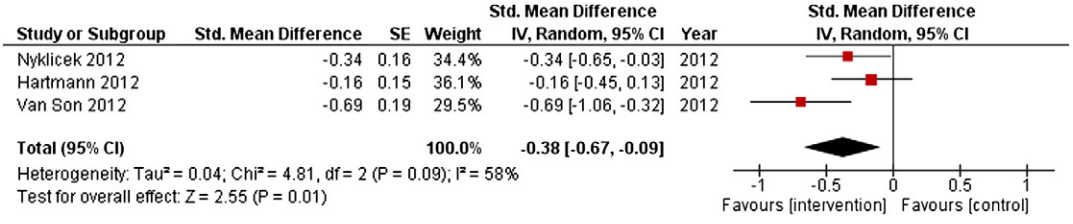

Fig. 4. Forest plot showing effects of MBSR/MBCT on stress.

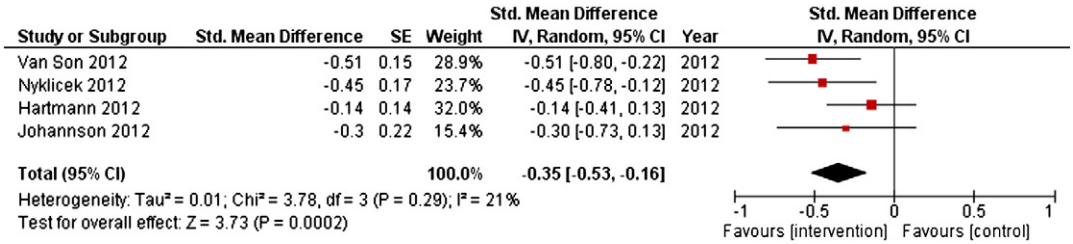

Fig. 5. Forest plot showing effects of MBSR/MBCT on depression.

[31]. The pooled results indicate significant moderate effects of MBSR for SBP, SMD −0.78 (95% CI −1.46 to −0.09, p = 0.03), and DBP, SMD −0.67 (95% CI −1.26 to −0.08, p = 0.03). The results for SBP are shown in Fig. 7, with DBP following an almost identical pattern (not shown).

Heterogeneity (I^2 = 89%) was high for both analyses, and observation of the forest plots show the study by de la Fuente et al. [34] reported markedly different effects from the other three studies. Of the four, de la Fuente et al. had the smallest sample size (n = 17) and the study population also had higher SBP and DBP at baseline (including those with both grades 1 and 2 hypertension). This may partly explain the greater effect size observed, though it could also be attributable to some other aspect of the intervention or intervention delivery. A repeat of the meta-analysis without inclusion of this study reduced the pooled effect size (as expected) and the effect, whilst still favouring intervention, was no longer significant for either SBP or DBP (SMDs −0.31, 95% CI −0.64 to 0.01, p = 0.06 and −0.29, 95 %CI −0.64 to 0.06, p = 0.11 respectively).

Other physical outcomes relate to measures of disease status/progression. The HEIDIS Study [31] is a large (n = 110) ongoing five year study assessing the effects of MBSR on outpatients with type 2 diabetes with microalbuminuria or albuminuria compared to treatment as usual. No significant effects of intervention were observed for the primary outcome measure of albuminuria, or secondary outcome measure of HbA1c at post-intervention, or at the one year follow-up. The DiaMind study [26] observed no effect of intervention on HbA1c immediately post intervention and Robert McComb et al. [33], found no effect of intervention on resting stress hormone levels or physical functioning for women with heart disease.

Discussion

This is the first systematic review and meta-analysis of mindfulness based therapy intervention for people with, or at risk of, vascular disease. Nine articles (eight RCTs), examining MBSR or MBCT interventions were included, and the effects on psychosocial and/or physical outcomes were assessed. The review confirms the findings from other systematic reviews in populations with somatic diseases and chronic pain, that mindfulness therapy appears effective for assisting with depression, anxiety and psychosocial stress [11,14]. Small to moderate beneficial effects were observed for stress (−0.36; 95% CI −0.67 to −0.09; p = 0.01), depression (−0.35; 95% CI −0.53 to −0.16; p = 0.003) and anxiety (−0.50; 95% CI −0.70 to −0.29; p < 0.001). These effect sizes are comparable with previous findings; SMDs of 0.53 for combined mental health outcomes across healthy and clinical populations [36] and 0.32–0.47 for anxiety, distress and depression in populations with chronic medical disease [14]. Since only two of the studies recruited participants based on pre-intervention mood states (low emotional well being [26] and mental fatigue [35]), it is plausible that this is an underestimation of the possible effects of MBSR and MBCT intervention for a population that is known to be at increased risk of psychosocial distress [3]. The evidence for the ability of MBSR and MBCT intervention to result in favourable physical outcomes was less clear: meta-analyses of four studies showing a small but limited effect on blood pressure for individuals with hypertension and diabetes, and two individual studies found no effect on markers of diabetes progression. These results are similar to findings from comparable meta-analyses in other clinical populations: Rainforth et al. [37] reported little evidence of effectiveness of stress-based therapies for those with high blood pressure, and Markowitz et al. [38] found one-to-one cognitive based therapy effective in improving depression but not markers of disease status in patients with diabetes with co-morbid depression.

Whilst the findings from this review are favourable for MBSR and MBCT intervention for vascular populations with regard to improving psychosocial health, a few caveats need to be considered. The majority of studies in this review employed a wait-list control which can lead to differences in expectancy effects, resulting in an overestimation of the treatment effect. That said, the use of an active control treatment (PMR) [24] resulted in a greater treatment effect than a wait-list control [30] in trials of patients with grade 1 hypertension. Use of a wait-list control also limits the generalisability of the findings to those who are agreeable to waiting per se. This was reflected in the low proportion of eligible people who agreed to participate in some studies [26], a number which was not always reported. Indeed, the potential bias of self-selection in this type of study design has been recognised previously [12,14,39]. There was also considerable drop-out in some of the included trials amongst the intervention groups. Whether tailoring the MBSR and MBCT interventions to better suit the specific needs of the clinical population would help reduce the drop-out rate is not known.

Few studies reported long term follow-up and this may be an important factor to consider for effects on physical outcomes. In the study by Hartmann et al. [31], significant beneficial psychosocial and physical effects for patients with diabetes were observed only one year after the MBSR intervention, but not immediately post intervention. The Hartmann et al. [31] study plans to follow up at 5 years, and the Van Son et al. [26] study plans to follow up at 6 months (only immediate post intervention results are publicly available so far), but the other studies reported no long term follow up. Lack of planned long term follow up for studies assessing mindfulness therapies has been noted by others [15]. Another potential reason for finding little effect of intervention on physical outcomes may be the normality, or marginally at-risk level, of some of the outcome measures at baseline. The meta-analyses on the hypertension studies within this review showed that intervention benefited most those with highest baseline blood pressures. Whilst

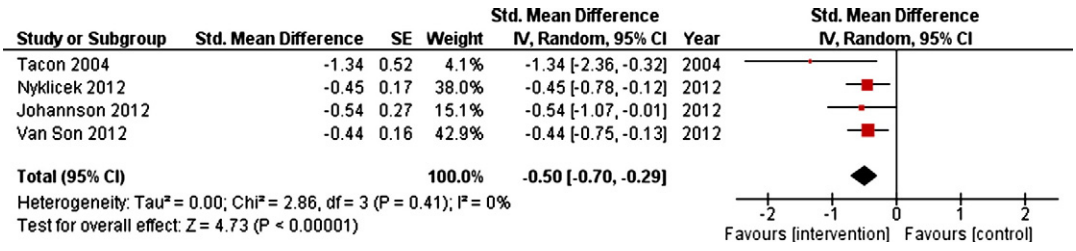

Fig. 6. Forest plot showing effects of MBSR/MBCT on anxiety.

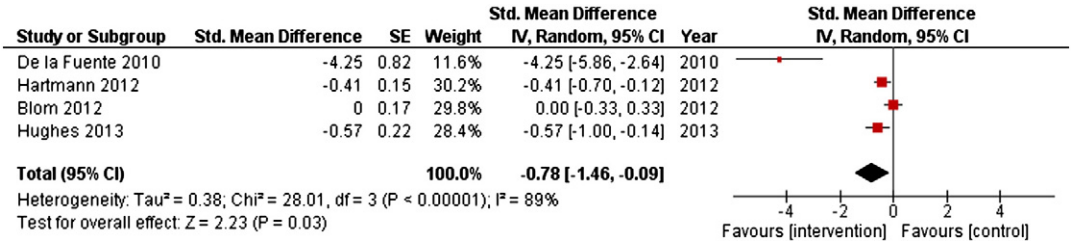

Fig. 7. Forest plot showing effects of MBSR/MBCT on hypertension.

this may have been due to chance or the small sample size of this study, or attributable to some other aspect of the population or a specific component of the intervention or its delivery, it may also have simply reflected a regression to the mean effect i.e. that the intervention works best for those farthest away from the mean/normal values. Indeed studies that reported outcome measures at baseline that approached normality, such as diabetes distress [26] and stress hormones [33], found no effect of the intervention on those measures. It was also interesting to note that whilst Hartman et al. [31], as noted earlier, observed no effects of intervention on depression in patients with diabetes immediately post intervention, which they attributed to the low presence of depression at baseline, they did observe benefits a year later. They attributed this to the MBSR intervention preventing progression into depression, suggesting that the effects of intervention accumulate with time. This supports the need for longer term assessments of mindfulness therapy interventions.

With only two trials reporting the degree of compliance with the intervention to either the weekly class attendance or degree of home practice, it was not possible to explore the impact of dose of intervention on outcomes. Nor was it possible in this review to address the mechanism of intervention. MBSR and MBCT are complex interventions and patients may benefit through one of several different mechanisms, for example mindful movement (yoga), increased physical activity generally, or greater self-compassion. Indeed the amount of mindful walking or mindful yoga engagement, reported in some of the studies [26,30], is likely to have varied across the interventions, and this could impact outcomes. Although the precise mechanism of action of mindfulness therapies is not known, increased mindfulness has been proposed to mediate improvement in functioning by reducing rumination and emotional avoidance and improving behavioural self-regulation [15]. However, mindfulness was assessed in only one [32] out of the eight RCTs. In this study, changes in mindfulness fully mediated the differences between controls and intervention regarding symptoms of anxiety, depression and quality of life. There is clearly a need for future studies to assess and report both on compliance and on mindfulness itself to help understand the critical attributes of mindfulness intervention.

Strengths and limitations

This is the first systematic review and meta-analysis of mindfulness based therapies for populations with, or at risk of, vascular disease. The review followed best practice guidelines for systematic reviews [22] and did not restrict by date or language, nor by whether studies had been published or not. Authors of papers who had published abstracts only, were contacted for their data, if available. In addition, authors were contacted for additional data to optimise our approach to meta-analysis (with five out of six authors assisting with this request).

The limitations mainly relate to study quality. In general, the reporting of the studies, especially with regard to compliance with the intervention, and detailed information on the components of the intervention was lacking. Furthermore, whilst in this type of study it is impossible to blind the participants with regard to treatment, there was poor reporting of whether there was blinding of outcome measures. Any exploration of whether specific attributes or dose of the intervention impacted on effectiveness were also prevented by lack of detail within the papers, along with a poor response to the request for manuals (though three authors did report making only small changes to the standard intervention approach already documented within the manuscripts). It should also be noted that we were limited to a relatively small number of studies for each of the outcome meta-analyses.

Implications for practice and research

Vascular disease is a leading cause of morbidity and mortality. There is a recognised need to equip patients with vascular disease with skills and coping strategies to help reduce or manage perceived psychological stress in the long-term and mindfulness-based approaches have been advocated as one promising psychosocial approach. This systematic review demonstrated that structured group-based mindfulness based interventions such as MBSR and MBCT may be beneficial in practice across a range of psychological and psychosocial issues encountered by individuals with vascular disease. Of note, was the fact that mindfulness intervention appeared to be effective despite the relatively low levels of baseline depression, anxiety and stress. This suggests that mindfulness may be of benefit to the perceived psychological health and emotional well-being of vascular disease populations with a broad spectrum of mood states not just those showing signs of distress. There is also scope that such interventions may also be of benefit to physiological functioning, though the short term studies to date do not support this. Future RCTs of MBSR and MBCT need to make provision for long term follow up to establish whether the benefits of intervention do accumulate with time as has been suggested.

It is unclear from the available studies what the time course of change in physical outcomes is and how they may compare with pharmacotherapy and more conventional behaviour change strategies. Future studies should consider the time course of change in physical and mental outcomes with mindfulness intervention. There also needs to be careful consideration given to the choice of the control group employed, preferably providing an active control group to minimise the potential bias of observed effects. Tailoring the intervention to suit the needs of the clinical population warrants further investigation.

Conclusions

Whilst populations with vascular disease appear to derive a range of psychological benefits from MBSR/MBCT intervention, their ability to impact on the physical parameters of disease is yet to be confirmed. More robust studies, with longer term follow-up, are required to establish full efficacy of such intervention.

Funding

This systematic review was funded by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South West Peninsula (PenCLAHRC). The funders had no role in the design or conduct of the review, data collection, analysis or interpretation, or approval of the manuscript. The views

expressed in this article are those of the authors and not necessarily those of the NIHR, or the Department of Health.

Competing interests

The authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; and no other relationships or activities that could appear to have influenced the submitted work.

Contribution of authors

WK and CD conceived the concept of the study and all authors contributed to the design of the study. RA, RW and AB screened and data extracted the literature. LR performed the data analyses, RA drafted the manuscript, and all authors commented on subsequent drafts and contributed to the discussion and implications.

Acknowledgements

We are grateful to the included paper authors (Hughes, Johansson, Nyklíček, Hartmann, Van Son) who provided additional data to assist with the meta-analyses.

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